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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,710	09/05/2000	Suman Preet Singh Khanuja	056859/0107	8287

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EXAMINER

COE, SUSAN D

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/655,710

Applicant(s)

KHANUJA ET AL.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,11-26 and 28-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 10, and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The amendment filed October 1, 2001, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1-48 are pending.
3. Claims 7, 8, 11-26, and 28-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.
4. Claims 1-6, 9, 10, and 27 are examined on the merits.

### ***Claim Rejections - 35 USC § 112***

5. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth on page 3 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that this claim is not indefinite because the claims states "that one gram of licorice contains the equivalent of 40 mg of glycyrrhizin." However, this is not an exact quote from the claim. As the claim current reads, it is not clear that this is the limitation. If the language of the claim stated clearly that one gram of licorice is equivalent to 40 mg of glycyrrhizin then the claim would be considered definite.

***Claim Rejections - 35 USC § 102***

6. Claims 1-5 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,939,050 for the reasons set forth on page 3 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that US '050 does not anticipate the stated claims because US '050 does not teach using *G. glabra* as a bio-enhancer or bioavailability facilitator. However, US '050 clearly teaches a composition that contains *G. glabra* and an anti-infective agent. This composition is the same as the claimed composition. Therefore, the since the compositions are the same, the composition taught by US '050 must have the same characteristics as the claimed composition if applicant's composition functions as claimed.

Applicant also argues that US '050 does not teach that one gram of licorice contains 40 mg of glycyrrhizin. However, this limitation is not reflected in claim 27. In addition, even if this limitation was clear, US '050 would still be considered to anticipate claim 27 because the *G. glabra* extract of US '050 appears to be the same extract that is used by applicant. Therefore, the extract of US '050 would contain the requisite amount of glycyrrhizin.

7. Claims 1-6 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,770,217 for the reasons set forth on page 3 and 4 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that US '217 does not anticipate the stated claims for the same reasons that applicant argued against the rejection over US '050. The examiner disagrees with the applicant for the reasons explained above.

***Claim Rejections - 35 USC § 103***

8. Claims 1, 6, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No 5,770,217 for the reasons set forth on page 4 and 5 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered and are not persuasive. Applicant states that US '217 teaches using *G. glabra* extracts to enhance the immune system and to function as an antibacterial and antiviral agent rather than as a bioavailability enhancer as claimed by applicant. Based on this difference, applicant argues that one of ordinary skill in the art would not be motivated to optimize the amount of *G. glabra* extract in the composition of US '217 to meet the limitations of applicant's claim because the *G. glabra* is being used for a different purpose. However, it is well known in the art that an amount of an ingredient can be modified to determine the most effective combination of elements. Despite the fact that US '217 does not specifically teach that the *G. glabra* is used for the same purpose as that of the applicant, an artisan of ordinary skill would still be motivated to optimize the composition taught by US '217. This optimization would lead to composition claimed by applicant.

Applicant also argues that the combination of the amounts *G. glabra* and antibacterial claimed is unobvious over US '217 based on unexpected results shown in Tables 1-4 on page 14-16 of the specification. However, this is not persuasive because the tables show that the antibacterial agents function better when *G. glabra* is added at low concentrations. Claims 1 and 7 of US '217 specifically teach adding *G. glabra* at low concentrations. Therefore, the combination of a low concentration of *G. glabra* and antibacterial is anticipated. In addition,

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Tables 1-4 show an increased antibacterial activity of a small amount of antibacterial agents.

The scope of the claims is much broader than the showing of unexpected results.

9. Claims 1, 5, 6, 9, 10, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,939,050, The Merck Index (Budavari et al. (eds) (1989), 11<sup>th</sup> edition, Merck & CO., Inc: New Jersey, entry numbers 2315, 6273, and 6617) and US Pat. No. 5,478,829 for the reasons set forth on page 5 and 6 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that there is no motivation to combine a *G. glabra* extract with antibacterial agents nalidixic acid, norfloxacin, ciprofloxacin, and sparfloxacin because the *G. glabra* extract used by applicant is not used as an antibacterial agent. However, US '050 clearly teaches that *G. glabra* extracts are antibacterial agents. The *G. glabra* extract of US '050 is the same as the *G. glabra* extract claimed by applicant. Based on this teaching, a person of ordinary skill in the art would be motivated to combine a *G. glabra* extract with other antibacterial agents.

Applicant also argues that a person of ordinary skill would not be motivated to optimize the amount of the ingredients in the composition because applicant is adding the *G. glabra* extract for a different purpose. However, this is not persuasive for the reasons stated above in paragraph number 8.

10. No claims are allowed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC  
December 3, 2001

  
**LEON B. LANKFORD, JR.**  
**PRIMARY EXAMINER**